

Application No. 10/054,331
Docket No. A4-1763
Amendment dated May 17, 2004
Reply to Office Action of December 17, 2003

REMARKS

In the Office Action, the Examiner reviewed claims 1-35 of the above-identified US Patent Application, with the result that the specification was objected to and all of the claims were rejected under 35 USC §103. In response, Applicants have amended the specification and claims as set forth above. More particularly:

The title of the invention has been amended at page 1 of the specification to be more descriptive of the invention recited in independent claim 1.

Paragraphs [0009], [0014] and [0015] have been amended to correct typographical and grammatical errors.

Paragraphs [0010] and [0012] through [0015] have been amended and paragraph [0011] has been deleted to render the summary of the invention more consistent with the invention recited in independent claim 1.

The specification has been amended at paragraphs [0029] and [0057] to correct inconsistencies with the drawings.

In amended Figure 6, the previously omitted reference number 92 has been added.

The claims have been amended to use the term "sensing device" so as to be consistent with the "Brief Summary of the Invention" and better distinguish between the "sensing device" and its "sensor" element.

Independent claim 1 has been amended to incorporate the limitation from its

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dependent claim 11 that the sensing device comprises a "monolithic" structure.

Independent claim 1 has been further amended to correct a typographical error and to specify that the sensing device is capable of being entirely implanted within a human body, the sensing device comprises a biocompatible monolithic structure, and the sensor and active circuitry are microfabricated. Support for the limitation that the device is "entirely implanted" and for the term "human body" is inherent from, for example, paragraphs [0060] and [0064] ("it is necessary to anchor the device 12 so that migration of the device 12 does not occur within the patient") and paragraph [0003] ("body of a patient"). Support for the limitation that the substrate, sensor, conductive path, and active circuitry are portions of the "monolithic structure" can be found in Figures 9-11. Support for the limitation that the monolithic structure is "biocompatible" can be found in paragraph [0045]. Support for the limitation that the sensor and active circuitry are "microfabricated" can be found in original paragraphs [0014] and [0015].

In view of its limitations being incorporated into claim 1, claim 11 has been amended to specify that the device is actually implanted and operating within the human body.

Dependent claims 6, 20, 32 and 34 have been amended to address potential matters of clarity.

Dependent claim 9 has been amended to specify that the displacement cavity is defined by a surface cavity in the substrate. Support for this limitation can be found in

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Figure 1.

Dependent claim 19 has been amended to specify that the cap layer is bonded to the substrate. Support for this limitation can be found in paragraph [0035].

Dependent claim 29 and 30 have been amended to recite structural limitations relating to the terms "proximity mode" and "touch mode." Support for these amendments can be found in paragraphs [0038] and [0039].

Finally, dependent claim 35 has been amended to recite that the housing comprises a recess providing intimate access to the sensor. Support for this amendment can be found at paragraph [0058].

Applicants believe that the above amendments do not present new matter. Favorable reconsideration and allowance of claims 1-35 are respectfully requested in view of the above amendments and the following remarks.

Objection to the Specification

The Examiner objected to the title of the invention as not being descriptive. In response, Applicants have revised the title, adhering to the description and scope of the invention as it is stated in the preamble of the independent claim.

First Rejection under 35 USC §103

Independent claim 1 and its dependent claims 3-8, 11-25, and 31-35 were

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rejected under 35 USC §103 as being unpatentable over either U.S. Patent No. 6,068,589 to Neukermans, U.S. Patent No. 5,531,787 to Lesinski et al. (Lesinski '787), U.S. Patent No. 5,984,859 to Lesinski (Lesinski '859) in view of U.S. Patent No. 5,509,280 to Zavracky, U.S. Patent No. 5,081,437 to Mosser et al. (Mosser), or U.S. Patent No. 5,259,248 to Ugai et al. (Ugai). Applicants respectfully request reconsideration of this rejection in view of the amendments presented above as well as the following comments.

Applicants' invention is directed to an implantable microfabricated sensing device capable of being entirely implanted within a human body for measuring a physiologic parameter of the body. With reference to Figure 9, which shows one of several embodiments within the scope of claim 1, a sensing device (112) is represented as comprising a biocompatible monolithic structure (120,144) that includes a substrate (120), a sensor (118) integrally formed with the substrate (120) and responsive to the physiologic parameter, at least one conductive path (196) integrally formed with the substrate (120) and sensor (118); and active circuitry (140) in proximity to the sensor (118) and electrically connected to the sensor (118) by the conductive path (196).

Under this §103 rejection, the Examiner explained that primary references Neukermans, Lesinski '787 and Lesinski '859 teach all of the "essential features" of the claimed invention, namely, the substrate, integral sensor, conductive path, and active circuitry "close to and electrically connected to the sensor." The Examiner

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acknowledged that the primary references fail to specifically teach a cap layer formed of boron doped silicon, but then cited Zavracky, Mosser and Ugai for such teachings.

As noted above, Applicants teach and claim a sensing device (112) in which a substrate (120), integral sensor (118), conductive path (196), and active circuitry (140) are all portions of a biocompatible monolithic structure (120,144), and that the entire sensing device (112) is implantable within the human body. In contrast, the primary references (Neukermans, Lesinski '787 and Lesinski '859) are all limited to implantable devices whose sensors (28) and their processing circuitry (30) are not part of the same monolithic structure - instead, the sensors (28) and their circuitry (30) are completely discrete components that are placed separately and apart in the body and interconnected only with wires (33,34). Furthermore, the devices taught by the primary references have sensor portions that do not sense physiologic parameters of and within the human body - instead, the sensors (microphones 28) of these devices sense sound waves outside the body.

The secondary references (Zavracky, Mosser and Ugai) do not suggest a biocompatible monolithic structure that includes an integrated microfabricated sensor and active circuitry. For example, the active circuitry that may be employed with the signal conditioning circuit 136 (Figures 12 and 13) of Zavracky is not disclosed or suggested as being on the same substrate 120 as the sensor 121. In addition, the secondary references do not teach or suggest devices that are or can be entirely

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implanted within the human body for sensing physiologic parameters of and within the body.

In view of the above, to arrive at Applicants' invention one skilled in the art would be required to modify the teachings of the primary references beyond that taught or suggested by the secondary references. However,

The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the *prior art* suggested the desirability of the modification. (Emphasis added.)

In re Fritch, 23 USPQ2d 1780, 1783-1784 (Fed. Cir. 1992).

Furthermore, for the basis of a rejection under 35 USC §103, Applicants believe that it is very significant that the primary and secondary references are not concerned with the problem solved by Applicants - namely, a microfabricated sensing device that can be entirely implanted within a human body for actively measuring a physiological parameter within the human body. Absent recognition of the problems faced and solved by Applicants, Applicants believe that the prior art does not suggest the sensing device recited in Applicants' claims. *Eibel Process Co. v Minnesota and Ontario Paper Co.*, 261 US 45 (1923).

Finally, Applicants believe that the combination of prior art references cited in this rejection do not teach or suggest other claimed aspects of the invention. For

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example, the prior art does not teach or suggest: a displacement cavity in communication with an interior volume (claim 9), two conductive paths isolated by a p-n junction (claim 28), a housing that defines a form factor providing an external shape to the sensing device (e.g., round) that differs from the monolithic structure (e.g., rectilinear) (claim 32), or that such a housing comprises a recess providing intimate access to the sensor (claim 35).

For all of the above reasons, Applicants respectfully request withdrawal of the first rejection to the claims under 35 USC §103(a).

Second Rejection under 35 USC §103

Dependent claims 2, 9, 10, and 26-30 were rejected under 35 USC §103 as being unpatentable over either Neukermans, Lesinski '787, or Lesinski '859 in view of Zavracky alone, which the Examiner cited for teaching a capacitive-type sensor. For the same reasons as set forth in Applicants' remarks to the first §103, rejection, Applicants respectfully request reconsideration and withdrawal of the second rejection to the claims under 35 USC §103(a).

Closing

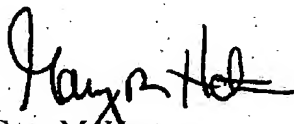
In view of the above, Applicants believe that all the rejections to their claims have been overcome, and that the claims define patentable novelty over all the

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references, alone or in combination, of record. It is therefore respectfully requested that this patent application be given favorable reconsideration.

Should the Examiner have any questions with respect to any matter now of record, Applicants' representative may be reached at (219) 462-4999.

Respectfully submitted,

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Attachments: Replacement Drawing Sheet